IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
EASTERN DIVISION

JIM HOOD, ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, *ex rel.* THE STATE OF MISSISSIPPI,

Plaintiffs,

v.

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, ASTRAZENECA PLC, ASTRAZENECA AB, and ASTRAZENECA UK LIMITED

Defendants.

Case No. 1:10CV104-SA-JAD

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca plc, AstraZeneca AB, and AstraZeneca UK Limited (collectively "AstraZeneca") respectfully submit this Opposition to Plaintiffs' Motion to Remand filed by the State of Mississippi ("State") and the State and Schools Employees Life & Health Plan ("Employees Plan") (collectively "plaintiffs").

INTRODUCTION

AstraZeneca exercised its statutory right to remove this action to federal court because complete diversity of citizenship exists between the parties. In addition, there is federal question jurisdiction under the Supreme Court's controlling decision in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), because the Complaint raises substantial and disputed issues of federal law. Either way, plaintiffs' motion to remand must be denied because AstraZeneca is entitled to have this matter adjudicated in a federal forum. None of plaintiffs' arguments or authorities require, much less permit, a different result.

First, the mere presence of the State as one of many parties on one side of the caption does not defeat diversity jurisdiction. The Fifth Circuit made that clear in *Hussain v. Boston Old Colony Ins. Co.*, 311 F.3d 623, 635 n.46 (5th Cir. 2002) (stating in a multi-party case that because "the government is not a citizen of any state, it is not considered in the complete diversity calculus"). The cases cited by plaintiffs are either inapposite or unpersuasive. Certainly none of them can diminish the force of *Hussain*. What is more, plaintiffs do not contest—and thus concede—that the Employees Plan is a separate and distinct entity from the State and therefore *not* its alter ego—making it a citizen of Mississippi for purposes of diversity jurisdiction.

Second, the remand of other cases presenting similar (but not identical) issues does not defeat federal question jurisdiction here. Those decisions did not address all of the grounds for federal jurisdiction argued by AstraZeneca in this case. Moreover, they conflict with numerous other decisions (correctly) denying remand in materially indistinguishable circumstances.[1] Those latter decisions reflect the better view of the law, and their results should obtain here as well.

Third, even if plaintiffs' policy concerns could take precedence over Congress's grant of jurisdiction, which they cannot, those concerns are misplaced. Allowing AstraZeneca to exercise its statutory right to have this case heard in federal court—consistent with Congress's purpose in vesting federal courts with diversity and federal question jurisdiction in the first place—is hardly

[1] The Zyprexa MDL judge has held on five additional occasions that the same types of claims at issue here raise substantial federal questions justifying exercise of federal question jurisdiction. *Montana ex rel. McGrath v. Eli Lilly & Co.*, Nos. 04-MD-1596 and 07-CV-1933, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008), attached as Exhibit A; *New Mexico, ex rel. Madrid v. Eli Lilly & Co.*, Nos. 04-MD-1596 and 07-CV-01749, 2009 U.S. Dist. LEXIS 20768 (E.D.N.Y. Mar. 11, 2009), attached as Exhibit B; *West Virginia ex rel. McGraw v. Eli Lilly & Co.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007), attached as Exhibit C; *Louisiana ex rel. Foti v. Eli Lilly & Co.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), attached as Exhibit D; *Mississippi, ex rel. Hood v. Eli Lilly & Co.*, Nos. 04-MD-1596, 07-CV-645, 2007 WL 1601482 (E.D.N.Y. June 5, 2007), attached as Exhibit E.

cause for alarm. Nor would it "upset" any division of state and federal authority. Federal courts, in ongoing MDL proceedings, are already exercising jurisdiction over many of the same issues raised by plaintiffs. Accordingly, plaintiffs' motion to remand should be denied.[2]

ARGUMENT

I. THE REMAND MOTION MUST BE DENIED BECAUSE THE REQUIREMENTS FOR DIVERSITY JURISDICTION ARE SATISFIED.

Plaintiffs make three key concessions that confirm AstraZeneca has carried its burden of showing the requirements for diversity jurisdiction are satisfied. *See Smith v. United States*, 328 F.3d 760, 770 (5th Cir. 2003) ("A party's concession of an issue means the issue is waived and may not be revived."); *Fehlhaber v. Fehlhaber*, 681 F.2d 1015, 1030 (5th Cir. 1982) ("Failure to brief and argue an issue is grounds for finding that the issue has been abandoned.").

First, plaintiffs concede that the Employees Plan is a real party in interest to this lawsuit. Pl's Mot. at 5; *see also* Notice of Removal at ¶¶ 9-11. Second, plaintiffs do not dispute that the Employees Plan is a separate and distinct entity from the State, and therefore a citizen of Mississippi for purposes of determining diversity jurisdiction. Pl's Mot. at 4-6; *see also* Notice of Removal at ¶¶ 13-16. Third, plaintiffs do not dispute that the jurisdictional amount is satisfied. Pl's Mot. at 4-6; *see also* Notice of Removal at ¶¶ 21-24. Accordingly, there is (1) complete diversity of citizenship, and (2) an amount in controversy in excess of $75,000.

Plaintiffs' only argument to the contrary is that the State's status as co-plaintiff with the Employees Plan destroys diversity jurisdiction. Pl's Mot. at 4-6. But that is a misreading of the diversity rule, which only precludes diversity jurisdiction "when *any* plaintiff is a citizen of the same State as *any* defendant." *Powell v. Offshore Navigation, Inc.*, 644 F.2d 1063, 1066 (5th

[2] So as not to burden the Court, AstraZeneca will not repeat the background, argument, and authorities set out in its Notice of Removal. Rather, AstraZeneca respectfully refers the Court to pertinent sections of the Notice of Removal by cross-referencing those sections in this Opposition.

Cir. 1981) (emphasis added). *No* plaintiff in this case is a citizen of the same state as any of the AstraZeneca defendants.

Any doubt that diversity jurisdiction exists here was dispelled by the Fifth Circuit in *Hussain*.[3] Although the Fifth Circuit ultimately held that removal was proper because federal question jurisdiction existed, the court went on to conclude that "subject matter jurisdiction on the basis of diversity would have been met" as well. 311 F.3d at 635, n.46. In explaining that complete diversity of citizenship existed, the Fifth Circuit could not have been clearer that "[a]s the [federal] government is not a citizen of any state, it is not considered in the complete diversity calculus." *Id.* That conclusion applies with equal force in the case at bar, where the State should not be "considered in the complete diversity calculus" either.

Ignoring *Hussain*, plaintiffs rely instead upon *In re Katrina Canal Litigation Breaches*, 524 F.3d 700, 706 (5th Cir. 2008). But *Katrina* did not address the issue before this Court. The question in *Katrina* was whether minimal diversity could be established under the Class Action Fairness Act ("CAFA"), and the court did not have to reach the impact of a state's status as co-plaintiff on a complete diversity analysis. *E.g.*, *id.* at 705 ("CAFA provides for removal of class actions involving parties with minimal diversity"); *id.* at 706 ("CAFA supplies federal jurisdiction" in cases involving "minimal diversity"); *accord id.* at 706-07. Instead, *Katrina* held that "minimal diversity" was established notwithstanding the presence of the State as a party, *id.* at 706, and that the exercise of diversity jurisdiction would not violate the Eleventh Amendment or offend any principle of sovereign immunity, *id.* at 706-11.

Plaintiffs' reliance on *Louisiana v. Union Oil Co.*, 458 F.3d 364 (5th Cir. 2006), is similarly misplaced. Pl's Mot. at 5-6. That case involved claims filed by the State of Louisiana

[3] In order to avoid re-arguing points conceded by plaintiffs in their Motion, AstraZeneca respectfully directs the Court's attention to pages 4-9 of the Notice of Removal, where defendants set forth the other reasons for federal diversity jurisdiction.

and a parish school board for damages inflicted on school lands owned by the State. *Id.* at 366. Both plaintiffs sought the same damages, under the same claims, in regards to the same state-owned property—thereby making it impossible for the court to distinguish the plaintiffs, let alone ignore the citizenship of the State in conducting a diversity analysis. *Id.* at 367. Likely for this reason, the defendants in *Union Oil* did not argue—and the Fifth Circuit did not consider—whether "complete diversity" existed due to the presence of a "citizen" defendant. The *only* question was whether the State was a real party in interest with respect to the indivisible property claims before the court.[4] In contrast, the State and the Employees Plan here seek separate and distinct damages (*see, e.g.*, Compl. ¶ 1.1), and not all of the claims are asserted on behalf of both parties. Compl. ¶¶ 15.1-15.6 (asserting claim on behalf of State only for violation of Mississippi Medicaid Law); 16.1-16.9 (same for violation of Mississippi Consumer Protection Act); 19.1-19.6 (same for negligence claim). Indeed, the plaintiffs here could have filed separate lawsuits against AstraZeneca for their damages, and the suit by the Employees Plan would be removable under § 1332.[5] Had the plaintiffs in *Union Oil* tried to file separate lawsuits, however, they would have violated the prohibition against claim-splitting. *See Channel v. Loyacono*, 954 So.2d 415, 424 (Miss. 2007) ("[A] single cause of action cannot be split so as to be properly made the subject of different actions[.]"). *Union Oil* is thus distinguishable from the case at bar.

Plaintiffs are left to rely upon *Hood v. Hoffman-LaRoche, Ltd.*, 639 F. Supp. 2d 25 (D.D.C. 2009), a non-binding district court opinion from another jurisdiction. Pl's Mot. at 5-6. But that case relies on a misreading of *In re Katrina* and the inapposite opinion in *Union Oil*.

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4 *See* Original Brief of Defendant-Appellee Exxon Mobil Corp., *Union Oil*, 458 F.3d 364, *available at* 2005 WL 6109503 (Exhibit F hereto); Original Brief of Defendant-Appellees Union Oil Co. et al., *Union Oil*, 458 F.3d 364, *available* at 2005 WL 6109502 (Exhibit G hereto).

5 For example, in *State of Mississippi v. Forrest Labs., Inc. et al.*, Case No. 3:09-cv-00086-MPM-DAS (N.D. Miss.), the State sued on behalf of the Employees Plan only, and the case was removed and transferred to MDL No. 1456 (D. Mass.), where it remains pending.

Furthermore, it fails to give proper credence to *Hussain* or the other courts that have concluded that a state "is not a citizen for diversity purposes" and thus its joinder "could not destroy the diversity jurisdiction already established." *Laird v. Chrysler Corp.*, 92 F.R.D. 473, 475 (D. Mass. 1981); *Grammer v. Melnik*, No. 2007-73, 2008 WL 501251, at *3 (D.V.I. Feb. 14, 2008) (holding that "it cannot be said that [the Government of the Virgin Islands] is a citizen of the Virgin Islands for purposes of defeating diversity jurisdiction"); *Union Pac. Ins. Co. v. Capital Dev. Bd. of the State of Ill.*, 482 F. Supp. 541, 546 (N.D. Ill. 1979) (holding that "[t]he joinder of [the state agency] would not contravene that [diversity] rule, since [the state agency], as we have held, is not a citizen for diversity purposes and thus is not a co-citizen of plaintiff").[6] The same is true here. AstraZeneca has established that the diversity jurisdiction requirements are satisfied, and plaintiffs' argument to the contrary must be rejected.

II. FEDERAL QUESTION JURISDICTION EXISTS UNDER *GRABLE*.

The Supreme Court has recognized "for nearly 100 years that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues." *Grable*, 545 U.S. at 312. This doctrine "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id*. This lawsuit presents such a case.

A. Federal Jurisdiction Exists Over State-Law Claims That Implicate Significant Federal Issues.

A plaintiff may not defeat removal by failing to plead necessary federal questions in its complaint. *See Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 22

[6] *LaFourche Parish Water District No. 1 v. Traylor Bros., Inc.*, No. 09-3204, 2009 U.S. Dist. Lexis 66265, at *4 (E.D. La. July 21, 2009), is inapposite. *Traylor* involved a state agency that both parties agreed was an alter ego of the state. Here, there is no dispute that the Employees Plan is a separate and distinct entity from the State.

(1983); *County of St. Charles v. Missouri Family Health Council*, 107 F.3d 682, 683-684 (8th Cir. 1997). Although a cause of action may be created by state law, when "the right to relief depends upon the construction or application of the Constitution or laws of the United States, and . . . such federal claim is not merely colorable, and rests upon a reasonable foundation," federal jurisdiction lies. *Smith v. Kan. City Title & Trust Co.*, 255 U.S. 180, 199 (1921). Under *Grable*, "arising under" jurisdiction exists over state law claims that "necessarily stated a federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 321 (citations omitted). In this "contextual enquiry," considerations such as the existence of a private federal right of action are "relevant to, but not dispositive of, the 'sensitive judgments about congressional intent' that [28 U.S.C.] §1331 requires." *Id.*[7]

Since the decision in *Grable*, numerous courts have concluded that federal jurisdiction exists over state-law claims in circumstances where, like here, substantial issues of federal law are embedded in a plaintiff's state law claims.[8] The same is true here, and plaintiffs' motion to dismiss must be denied.

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[7] *Grable* also abrogated cases that interpreted *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986), to mean that "a private federal remedy for violating a federal statute is a prerequisite for finding federal question jurisdiction."

[8] *See, e.g.*, *Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1234-35 (10th Cir. 2006) (holding that plaintiff's state-law trespass and unjust enrichment claims against railroad raised substantial federal question because they required plaintiff to show that railroad's installation of fiber-optic cable along its right-of-way was a misuse of the federally granted right of way); *Municipality of San Juan v. Corporacion Para El Fomento Economico De La Ciudad Capital*, 415 F.3d 145, 148 n.6 (1st Cir. 2005) (where propriety of defendant's conduct "turns entirely on its adherence to the intricate and detailed set of federal regulatory requirements, and the funds at issue are federal grant monies," federal question jurisdiction proper under *Grable*); *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194-96 (2d Cir. 2005) (complaint raised substantial federal question, creating federal question jurisdiction, where state-law claims required court to decide whether defendants violated Communications Act of 1934); *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (holding that interpretation of "average wholesale price" provision of federal Medicare statute raises substantial federal question and that assertion of federal jurisdiction was "unlikely to upset any balance because of the substantial number of similar cases that are already pending in federal courts"); *State of California v. Powerex Corp.*, No. Civ-S-05-01216 DFL DAD, 2006 WL 997717, at *4 (E.D. Cal. Apr. 14, 2006) (holding that state-law claim regarding energy sales at out-of-market (OOM) rates "involve[d] a substantial federal question because . . . [the Federal Energy Regulatory

B. Plaintiffs' Complaint Raises Substantial and Disputed Questions of Federal Law.

1. Plaintiffs' Prima Facie Case Depends on the Interpretation of Federal Medicaid Law and the Resolution of Disputed Issues Involving the Interplay of State and Federal Law.

Resolution of plaintiffs' claims turns on a determination of the State's obligations under federal Medicaid law with respect to reimbursement for prescriptions of Seroquel. *See New Mexico ex rel. Madrid v. Eli Lilly and Co.*, Nos. 04-MD-1596 and 07-CV-01749, 2009 U.S. Dist. LEXIS 20768, at *68 (E.D.N.Y. Mar. 11, 2009). Specifically, whether the State can establish a *prima facie* case under its state law claims will depend on the interpretation and application of federal statutory provisions governing the circumstances when states must reimburse claims for costs of prescription medicines. *Id.* (exercising federal question jurisdiction over similar state claims and explaining that "[t]he factors enumerated in previous denials of motions to remand apply to this case: (1) prescription drugs such as Zyprexa are closely and exclusively regulated by the Food and Drug Administration, a federal agency; (2) Medicaid prescription drug benefits are administered according to federal laws and regulations; and (3) Medicaid is primarily funded by the federal government.") (citations omitted).

a. The Medicaid program establishes federal requirements for prescription drug coverage.

The Medicaid program "is a cooperative one" between the federal government and participating states which conditions federal funding on a participating state's compliance with federal statutory requirements. *Arkansas Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006). Participating states receive funding from the federal government that covers all

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Commission] has the exclusive authority to decide whether power is or is not in-state or OOM and whether a given quantity of wholesale electricity can be legally sold at OOM rates"); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1031 (N.D. Cal. 2005) (holding that state-law claims relating to overcharging for medicines raised substantial federal question under federal Medicaid statute and federal price-control statute).

or part of the cost of medical assistance that the states provide to their qualifying residents. *See* 42 U.S.C. § 1396, *et seq.* "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Medicaid Act . . . and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Virginia Hosp. Ass'n.*, 496 U.S. 498, 502 (1990).[9]

Medicaid is implemented through agreements, known as "state plans," between the federal government and participating States, wherein the States certify that they will comply with federal requirements. To qualify for federal funds, a State must submit its plan to the Secretary of Health and Human Services ("the Secretary") for approval. *See* 42 U.S.C. § 1396a(a), (b). A state plan defines the categories of individuals eligible for benefits and the specific kinds of medical services that are covered. *See* 42 U.S.C. § 1396a(a)(10)(A)(i). Each plan must provide "at least the care and services" specified by the Medicaid Act, which are referred to as the "minimum settings." 42 U.S.C. § 1396a(10)(A) (stating that state plans must "at least" provide the care and services listed in paragraphs (1)-(5), (17), and (21) of 42 U.S.C. § 1396d(a)); 42 U.S.C. § 1396d(a).

In addition to the "minimum settings," states may provide additional benefits, such as coverage for prescription drugs. 42 U.S.C. § 1396b(i)(10)(A). If a state elects to provide a prescription drug benefit, as Mississippi has done, it must comply with certain minimum federal requirements set forth in 42 U.S.C. § 1396r-8, the Medicaid Drug Rebate Statute. This statute has two basic requirements. First, in order for a medicine to qualify for federal funding, the

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[9] As recognized by the Fourth Circuit in *Strawser v. Atkins*, 290 F.3d 720, 724-25 (4th Cir. 2002), because federal law requires states to require Medicaid recipients to assign any rights they possess against third parties to the state, "[f]ederal law also governs a participating state's distribution of any recovery on a third-party claim assigned by a Medicaid recipient." The federal governance of third-party payor recoveries stems from the fact that the federal government is entitled to a portion of the funds recovered by a state under an "assignment." *Id.* As such, the federal government is a real party in interest in these third-party payor cases, thus providing an additional ground for this case to be in federal court.

manufacturer must have entered into a Medicaid Rebate Agreement with the Secretary, under which the manufacturer agrees to provide the drug to state Medicaid programs at favorable prices.[10] Second, once a drug manufacturer enters into a rebate agreement for a "covered outpatient drug," participating states *must* provide coverage for that drug under their plans, subject only to exclusions, restrictions, and procedures specifically delineated in the federal Medicaid statute.[11]

A "covered outpatient drug" is a drug that "is approved for safety and effectiveness as a prescription drug" by the FDA[12] and that is prescribed for outpatient use (subject to some exceptions)[13] for a "medically accepted indication."[14] The "term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the [FDCA] . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in" the statute:[15] (1) the American Hospital Formulary Service Drug Information ("AHFS"), (2) the United States Pharmacopeia-Drug Information ("USPDI"), and (3) the DRUGDEX Information System ("DRUGDEX"). With limited exceptions specified by federal law, as long as a use is supported by one of these three compendia, even if the use is not FDA-approved, *i.e.*, is "off-label," federal Medicaid law *requires* participating states to pay for the use.[16] *See, e.g.*, *Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006) (concluding that

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10 *See* 42 U.S.C. § 1396r-8(a)(1), (c); *see also Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

11 *See* 42 U.S.C. § 1396r-8(d); *see also Pharm. Research*, 538 U.S. at 652.

12 42 U.S.C. § 1396r-8(k)(2).

13 42 U.S.C. § 1396r-8(k)(3)(A)-(H).

14 42 U.S.C. § 1396r-8(k)(3).

15 42 U.S.C. § 1396r-8(k)(6).

16 It is long-settled law that physicians may prescribe FDA-approved drugs for any use that, in the physician's medical judgment, will best serve the patient. A "physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA. . . . [T]he prescription of drugs for unapproved uses is commonplace in modern medical practice

Florida's attempt to limit coverage of psychiatric drug Neurontin violated federal law because it restricted coverage of non-FDA-approved uses listed in AHFS and DRUGDEX); *see also Weaver v. Reagan*, 886 F.2d 194, 200 (8th Cir. 1989) (finding federal Medicaid statute prohibited Missouri from restricting coverage of AZT prescribed to AIDS patients for non-FDA approved indications where their physicians have certified that AZT is a "medically necessary" treatment).

The Medicaid statute constitutes a complex body of federal law regulating the circumstances under which a participating state may exclude or otherwise restrict coverage of a "covered outpatient drug" such as Seroquel. 42 U.S.C. § 1396r-8(d). For example, a participating state may, under certain circumstances, deny reimbursement if the prescribed use is not "medically accepted." 42 U.S.C. § 1396r-8(d)(1)(B)(i), k(6) (citing 21 U.S.C. § 301). A state may also deny reimbursement if a medicine subject to a rebate agreement has been excluded from the state's formulary pursuant to the procedures described in 42 U.S.C. § 1396r-8(d)(4)(C). 42 U.S.C. § 1396r-8(d)(1)(B)(iv). Resolution of the State's claims here will involve disputed issues under this body of federal law.

b. Plaintiffs' Complaint raises disputed federal questions regarding the prescriptions state Medicaid programs must include for reimbursement.

The State's right to recover on its claims seeking reimbursement of prescriptions under Medicaid depends upon the interpretation and application of the federal statutory provisions governing when a participating state may limit or exclude coverage for a prescription medicine. When a state takes legal action pursuant to its own state law, but its action exceeds its authority

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and ubiquitous in certain specialties." *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000); *see also Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989) ("[T]he fact that FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate."). The FDA, which has no authority to regulate the practice of medicine, has long recognized the benefits of off-label use of drugs. *See Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4, 5 (1982).

under federal Medicaid law, there is a paramount federal interest that warrants federal jurisdiction. *See Ahlborn*, 547 U.S. 268. In *Ahlborn*, the Arkansas Department of Health & Human Services, acting pursuant to state law, asserted a statutory lien to the settlement proceeds of an Arkansas Medicaid recipient; the Supreme Court concluded that in doing so, the state had violated federal Medicaid law. *Id.* at 274. *Ahlborn* exemplifies the federal interest at stake when a state contravenes federal Medicaid law.

In this case, the State of Mississippi is asserting that, but for AstraZeneca's alleged fraud, it would not have reimbursed for certain prescriptions of Seroquel. Resolving that issue, however, will require a determination of what federal law permits and does not permit, and whether State officials chose to take action permitted by federal law.

2. Plaintiffs' Allegations of FDCA Violations Through Off-Label Promotion Raise Substantial Questions of Federal Law Not Previously Considered by this Court.

In arguing that this case depends solely on violations of state law, plaintiffs rely heavily on *Mississippi v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, Civ. A. No. 1:08CV166-SA-JAD, slip op. at 1 (N.D. Miss. Mar. 4, 2009) ("*Janssen*"). In that case, this Court concluded that "Defendants' liability will solely depend upon its breach of duties as defined and created by state law." *Id.* at 4. But whether the State can recover funds it spent for reimbursing Seroquel prescriptions here depends on the interpretation of *federal* Medicaid statutes governing when states must reimburse for prescription medicines.[17] Similarly, this Court reasoned that "if the

[17] Plaintiffs also rely on *Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d 576 (E.D. Pa. 2007). But that case did not involve, and thus the district court there did not address, all of the federal issues presented in this case. Moreover, to the extent *Eli Lilly* held that federal jurisdiction cannot exist under *Grable* merely because independent state-law claims are present, *see* 511 F. Supp. 2d at 580, it is simply incorrect. Under 28 U.S.C. § 1441(c), when non-removable claims are joined with any claim removable under 28 U.S.C. § 1331, "the entire case may be removed." *See also Nicodemus*, 440 F.3d at 1235 n.8 ("If any one claim within Plaintiff's complaint supports federal question jurisdiction, a federal court may assert jurisdiction over all the claims, including any alleged state-law claims, arising from the same core of operative facts."). Because at least one of plaintiffs' claims here requires resolution of "substantial" and "disputed" federal questions, the requirements for federal question jurisdiction are satisfied under *Grable*.

State proves at trial that Defendants violated the Federal Medicaid Act, it would not necessarily follow that they committed Medicaid fraud as defined in Miss. Code Ann. § 43-13-213." *Id.* But while it may be true that proof of a violation of the Federal Medicaid Act is not sufficient to show a violation of the Mississippi Medicaid Law, in this case plaintiffs cannot show a violation of the Mississippi Medicaid Law without first showing violations of federal law.

There can be no real question that the Complaint bases its claims on violations of federal law. Plaintiffs are wrong to argue (at 2) that "[n]one of the State's state-law claims allege that a violation of the federal Medicaid Act or the Food Drug & Cosmetics Act ("FDCA") gives rise to Defendants' liability." To the contrary, plaintiffs premise their claims on allegations that AstraZeneca violated federal law through communications about non-FDA-approved uses of Seroquel. *See, e.g.*, Compl. ¶¶ 12.25, 12.27, 12.28, 12.29, 12.30, 12.31, 12.32, 12.33, 12.34, 12.35, 12.37, 12.38. The entire premise of plaintiffs' injury is that AstraZeneca's representations about Seroquel's off-label uses caused injury and harm to users who were prescribed Seroquel outside of its recommended indications. *See Montana*, 2008 WL 398378, at *5 ("[T]here is no state-law equivalent of 'off-label.' The concept is entirely federal.").[18]

Plaintiffs' off-label claims implicate a complex scheme of federal statutes and FDA regulations that permit pharmaceutical manufacturers to disseminate certain kinds of information regarding off-label uses of medicines. For example, the FDA and Congress have established "safe harbors" by which pharmaceutical manufacturers may disseminate information related to off-label use. *See, e.g.*, Notice from FDA regarding *Henney*, 65 Fed. Reg. 14286-01, 14287

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[18] AstraZeneca disputes plaintiffs' allegations that it has violated federal law, including specifically the allegation that it violated the FDCA by illegally communicating about Seroquel's off-label uses. AstraZeneca does not concede that these alleged violations of federal regulatory requirements are appropriate for judicial resolution or in any way relevant to whether plaintiffs can establish the claims at issue in this case. Nevertheless, since plaintiffs have included these federal issues as a substantial basis for their claims in this case, it is necessary and appropriate for the Court to consider them in connection with this threshold jurisdictional analysis.

(Mar. 16, 2000) (noting that "FDA traditionally has recognized the important public policy reasons to permit industry support for the full exchange of views in scientific and educational discussions, including discussions of 'new [off-label] uses'"); FDA, *Guidance for Industry, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* ("FDA Guidance") (Jan. 2009), *available at* http://www.fda.gov/oc/op/goodreprint.html (last visited May 17, 2010) (outlining mechanisms for pharmaceutical manufacturers to disseminate specified materials on off-label uses subject to certain requirements); *see also* the FDAMA. Because AstraZeneca's marketing and promotion of Seroquel is subject to such extensive federal regulation, whether communications by AstraZeneca are improper, off-label communications is a determination that can only be made pursuant to the federal statutes and regulations governing off-label promotion. *See Montana*, 2008 WL 398378, at *5 ("[Montana's] . . . off-label marketing claims will therefore necessarily raise substantial federal questions by requiring the court to interpret the meaning of the FDCA and its implementing regulations.").

Plaintiffs' allegations of improper off-label promotion not only require an analysis of whether AstraZeneca failed to comply with the FDCA, FDAMA, FDA Guidance, and accompanying regulations. They also require an analysis of the First Amendment. This issue is complex and the lines are often uncertain until litigated. *See generally* Notice from FDA regarding *Henney*, 65 Fed. Reg. at 14287 (describing years of constitutional litigation concerning these issues); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (describing orders enjoining the FDA, on First Amendment grounds, from enforcing certain statutes and regulations purporting to restrict certain off-label communications by

pharmaceutical and medical-device manufacturers). Because no argument concerning the First Amendment was made in *Janssen*, this Court's ruling did not address that issue.

This inquiry is especially important because unnecessary and unduly burdensome regulation of drug manufacturers' speech would not only implicate First Amendment protections, but also harm the public:

> As off-label uses are presently an accepted aspect of a physician's prescribing regimen, the open dissemination of scientific and medical information regarding these treatments is of great import. The FDA acknowledges that physicians need reliable and up-to-date information concerning off-label uses. 'More generically, we certainly believe it's very appropriate for physicians to get information about off-label uses from the many sources that they get them. And, of course, they get them from [Continuing Medical Education]; they get them from on-line databases; they get them through textbooks; they get them through discussions with colleagues; they get them through going to a medical center and grand rounds…. FDA does not desire or intend to interfere with that process.'

Friedman, 13 F. Supp. 2d at 56 (internal quotations and citation omitted). Plaintiffs' allegations—that unlawful, off-label promotion of Seroquel caused injury to plaintiffs—should be adjudicated in a federal forum under the federal laws and regulations promulgated by Congress and the FDA. What was true in *Grable* is true here as well: This case "turns on" federal law, as the Complaint directly raises substantial and disputed issues of federal law. These federal issues should be resolved in a federal forum.

C. The Federal Questions Embedded in Plaintiffs' State-Law Claims are Substantial.

In disputing the "substantiality" of the federal questions embedded in the Complaint, plaintiffs rely primarily on *Merrell Dow* and *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677 (2006). The federal issues implicated in this case, however, are significantly greater than in either *Merrell Dow* or *Empire*. To be sure, where the only federal question(s)

involved are mere peripheral issues, the requirement of "substantiality" is not met. *See Empire*, 547 U.S. at 700-01 (holding that substantiality requirement not met where only federal issue was a tag-along issue related to the calculation of damages). But plaintiffs' attempt (at 13-17) to read *Empire* and *Merrell Dow* so broadly as to condition federal question jurisdiction on the existence of a private right of action finds no support in those decisions or in any other. Indeed, the Supreme Court in *Grable* expressly rejected that reading of *Merrell Dow*, holding instead that a federal statute which gives rise to a state claim need not create a private remedy for the "substantiality" requirement to be satisfied and federal question jurisdiction to exist. *See* 545 U.S. at 317, 319-20 (finding "no good reason to shirk from federal jurisdiction over the dispositive and federal issue at the heart of the state-law title claim").[19]

Plaintiffs' argument that *Empire* requires remand is also meritless. *Empire* involved a claim by an insurance carrier providing health benefits pursuant to a contract with the federal government. The United States argued that the carrier's reimbursement claim arose under federal law because "federal law is a necessary element of the [carrier's] claim for relief." *Empire*, 547 U.S. at 690. But the sole issue requiring interpretation of federal law in *Empire* was "[the] extent, if any, to which the reimbursement should take account of attorney's fees expended . . . to obtain the tort recovery." *Id.* at 701 (quotation omitted). The Supreme Court held that this tag-along issue of calculating damages was not "substantial" enough to support federal jurisdiction under *Grable* for what was essentially a state-law breach-of-contract claim.

In contrast, the Complaint here raises important issues of *liability* under the FDCA, FDAMA, FDA regulations, and federal Medicaid law—not to mention important protections of

[19] *Merrell Dow* also involved substantially different facts. In that case, the violation of federal law merely raised a "rebuttable presumption," 478 U.S. at 806, 812. Here, in contrast, plaintiffs' prima facie case depends on proof of off-label promotion in violation of federal law and requires a determination of the State's obligations under the complex federal Medicaid scheme.

the First Amendment—"that sensibly belong[] in a federal court." *Grable*, 545 U.S. at 315. As one court put it, "[a]t issue here is not simply a federal standard, but also the added factor of an intricate federal regulatory scheme including detailed federal funding provisions, requiring some degree of national uniformity in interpretation." *West Virginia ex rel. McGraw*, 476 F. Supp. 2d at 234. Thus in analogous contexts, courts have concluded that state-law claims against drug companies for reimbursement of Medicaid funds raised substantial questions of federal law under *Grable*.

For example, in *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005), the court held that federal question jurisdiction existed under *Grable* because the plaintiff's state-law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. *Id.* at 1031. In reaching that conclusion, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." *Id.* at 1027. The court noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, *and those that impact a complex federal regulatory scheme*." *Id.* (emphasis added). Under that measure, the federal issues here are substantial, as well.

More recently, the MDL transferee judge for the Average Wholesale Price ("AWP") litigation held "that the meaning of AWP in the federal Medicare statute is a substantial federal issue that properly belongs in federal court." *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F. Supp. 2d 77, 80 (D. Mass. 2006). The court explained:

> The interpretation of AWP under the statute determines whether the Arizona Medicare beneficiaries … overpaid on their drug co-payments. Furthermore, once the meaning of AWP is determined, it can be applied to the many pending similar pharmaceutical drug pricing cases in the Medicare context. … As the judge assigned the

> massive multi-district litigation, involving class actions and numerous attorney general suits, I conclude that the issue of the meaning of AWP under the federal Medicare statute has national significance. A federal forum provides experience, solicitude and uniformity on this important federal issue.

Id. at 80-81. In reaching that conclusion, the court—informed by its experience grappling with the issue in numerous cases as part of the MDL over which it presides—expressly rejected the contrary approach taken in *Pennsylvania v. TAP Pharmaceutical Products., Inc.*, 415 F. Supp. 2d 516 (E.D. Pa. 2005), cited by plaintiffs. *See In re Pharm. AWP Litig.*, 457 F. Supp. 2d at 81. Whatever its merit, the *TAP* decision is easily distinguishable. In that case, unlike this one, there was no actually disputed federal question, and removal was untimely. *TAP*, 415 F. Supp. 2d at 525-27. Further, *TAP* involved a term that was no longer part of current federal law and that the Court found not to be central to the outcome of the case. *Id.* at 525. Here, in contrast, the dispute centers on a standard, "medically accepted indication" (among other federal issues) that is not only current but also determinative of the case.

In sum, this lawsuit raises an array of federal issues involving a complex federal regulatory scheme, federal statutes, federal regulations, federal preemption, and the First Amendment. These federal issues are substantial by any reasonable measure. They therefore belong in federal court.

D. Federal Jurisdiction Over This Case Will Not Upset the Balance of Federal and State Judicial Responsibilities.

Under *Grable*, if a case presents substantial, disputed federal questions, and assertion of federal jurisdiction over the case "would not materially affect, or threaten to affect, the normal currents of litigation" or cause other "threatening structural consequences," then "there is no good reason to shirk from federal jurisdiction." 545 U.S. 308, 319-20. This case involves multiple federal questions that a court must resolve to determine whether plaintiffs can satisfy

the elements of their claims. Because this case presents a unique combination of complex and unsettled federal questions, it is:

> [u]nlike the situation addressed by the *Merrell Dow* court, where finding federal jurisdiction over a state cause of action that implicated a federal standard might have led to a significant rise in the caseload of the federal courts, [and] this case does not pose such a threat.

West Virginia, 476 F. Supp. 2d at 234 (citation omitted). Indeed, the exercise of federal jurisdiction over claims like plaintiffs' poses no conceivable threat to the "normal currents of litigation."

Assertion of federal jurisdiction would not upset any delicate federal-state judicial division of labor, violate any congressional intent, or open the gates to "a horde of original filings and removal cases raising other state claims with embedded federal issues." *Grable*, 545 U.S. at 318. Allowing plaintiffs' claims to be adjudicated by a federal court would not "disturb[] any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314 (holding that federal jurisdiction is proper when "resolv[ing] genuine disagreement over federal [law] . . . provisions will portend only a microscopic effect on the federal-state division of labor").

Moreover, exercising jurisdiction over this case hardly "herald[s] a potentially enormous shift of traditionally state cases into federal courts." *Id.* at 319. Not every FDCA-related suit necessarily involves substantial federal questions. But there are some that do. And this is one of them. Plaintiffs are asserting claims that implicate complex federal regulations over prescription drug marketing and labeling, as well as the scope and requirements of Medicaid prescription drug coverage under the federal Medicaid statute. Such claims command a federal forum. *See, e.g.*, *West Virginia*, 476 F. Supp. 2d at 234; *In re Zyprexa*, 375 F. Supp. 2d 170; *Edmonds*, 417 F. Supp. 2d at 1341. Plaintiffs' motion to remand must therefore be denied.

CONCLUSION

For the reasons set forth above, AstraZeneca respectfully requests that the Court deny plaintiffs' Motion to Remand.

Dated: May 17, 2010 By: s/Stephen L. Thomas

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CERTIFICATE OF SERVICE

I hereby certify that on May 17, 2010, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to the following:

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